

CHILDRENS DELSYM COUGH PLUS CHEST CONGESTION DM-
dextromethorphan hydrobromide and guaifenesin solution
RB Health (US) LLC

Children's Delsym®

Cough Plus® **Chest Congestion DM**

Drug Facts

<i>Active ingredients (in each 5 mL)</i>	<i>Purposes</i>
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help your child get to sleep

Warnings

Do not use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

When using this product do not use more than directed

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **this product does not contain directions or complete warnings for adult use**
- do not give more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor

Age (year)	Dose (mL)
children 6 to under 12 years of age	5 mL - 10 mL every 4 hours
children 4 to under 6 years of age	2.5 mL - 5 mL every 4 hours
children under 4 years of age	do not use

Other information

- each 5 mL contains: **sodium 3 mg**
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate ¹, xanthan gum

¹ may contain this ingredient

Questions?

1-866-682-4639

You may also report side effects to this phone number.

Dist. by: RB Health (US), Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC 63824-214-64

Ages 4 Years +

Children's

Delsym[®]

COUGH +[®]

Chest Congestion

DM

Dextromethorphan HBr (Cough Suppressant)

Guaifenesin (Expectorant)

- Relieves Cough
- Relieves Chest

Congestion

- Thins &

Loosens

Mucus

Cherry Flavor

4 fl oz (118 mL)

children's Delsym[®]
COUGH+ CHEST CONGESTION
DM

Day
NDC 63824-214-64
children's Delsym[®]
COUGH+ CHEST CONGESTION
DM

children's Delsym[®]
COUGH+ CHEST CONGESTION
DM

Each dose of cherry flavored
Children's Delsym[®]
Cough+ Chest Congestion Liquid

- Relieves Cough
- Relieves Chest Congestion
- Thins & Loosens Mucus

Dosing cup included

cherry
Flavored Liquid
4 fl oz (118 mL)

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1-866-682-4639 or www.delsym.com

Drug Facts
Active ingredients (in each 5 mL):
Dextromethorphan HBr 5 mg Cough suppressant
Guaifenesin 100 mg Expectorant

Purposes
Cough suppressant
Expectorant

Uses
• helps loosen phlegm (mucus) and thin mucous secretions to so the bronchial passageways of asthmatics (mucus) and make coughs more productive
• temporarily relieves:
• cough due to minor throat and bronchial irritation as may occur with the common cold or sinusitis
• too intensity of coughing
• the impulse to cough to keep your throat from getting so dry

Warnings
Do not use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the MAOI drug, if you or not some of your other's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
Ask a doctor before use if the child has:
• persistent or chronic cough such as occurs with asthma
• cough that occurs with too much prescription product
when using this product do not use more than directed
Stop use and see a doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent hoarseness. These could be signs of a serious condition.
Keep out of reach of children. In case of overdose, get medical help and contact a Poison Control Center right away.

Directions
• this product does not contain directions or complete warnings for adult use
• do not take more than 6 doses in any 24-hour period
• measure only with dosing cup provided
• do not use dosing cup with other products
• use as directed or as directed by a doctor

Age Range	Dose (mL)
children 6 years to under 12 years of age	5 mL - 10 mL, every 4 hours
children 4 years to under 6 years of age	2.5 mL - 5 mL, every 4 hours
children under 4 years of age	do not use

Other information
• each 5 mL contains: dextrom 5 mg

Drug Facts (continued)
• store at 20-25°C (68-77°F)
• do not refrigerate

inactive ingredients
sulfuric acid, citrate sodium, FD&C no. 40, flavors, glycerin, propyl glycol, polyethylene glycol, purified water, sodium benzoate, sorbitol, sucrose, titanium dioxide, xanthan gum
*may contain this ingredient

Questions? 1-866-682-4639
You may also report side effects to the phone number.

Keep carton for full information.
Please visit our website:
www.delsym.com

PARENTS:
Learn about this risk by visiting:
www.StopMedicineAbuse.org

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CHILDRENS DELSYM COUGH PLUS CHEST CONGESTION DM

dextromethorphan hydrobromide and guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-214
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-214-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/31/2013	08/31/2019
2	NDC:63824-214-64	1 in 1 CARTON	06/08/2017	
2		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/31/2013	

Labeler - RB Health (US) LLC (081049410)

Revised: 6/2024

RB Health (US) LLC